

Dallas District 4040 North Central Expressway Dallas, Texas 75204-3145

January 12, 2005

Ref: 2005-DAL-WL-11

WARNING LETTER

CERTIFIED MAIL RETURNED RECEIPT REQUESTED

Mr. William L. Brown, Owner Brown Cattle Company 1 Feed Lot Road P.O. Box 281 Petrolia, TX 76377

Dear Mr. Brown:

An inspection of your ruminant feeding operation located at 1 Feed Lot Road, Petrolia, Texas, was conducted on August 24 and September 8, 2004 by an Investigator from the Food and Drug Administration (FDA). The inspection found significant deviations from the requirements set forth in Title 21, <u>Code of Federal Regulations</u>, Part 589.2000 – Animal Proteins Prohibited in Ruminant Feed (21 CFR 589.2000). This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

Our inspection revealed that you feed prohibited material, as defined by 21 CFR 598.2000(a), to ruminants. This prohibited material consists of human food processing waste, which is derived from corn dog manufacturing and contains hot dogs and corn dogs. Inspected meat products that have been cooked and offered for human food and further heat processed for animal feed are not prohibited material. This is more fully described in Guidance for Industry 76, which was previously provided to your firm. The human food processing waste you are using has not been further heat processed. The failure to further heat process this material causes the feed to be adulterated within the meaning of Section 402(a)(2)(C)(i) of the Federal, Food, Drug, and Cosmetic Act.

During our previous inspection on January 17, 2002, copies of the BSE Guidance documents 69, 70 and 76 and 21 CFR 589.2000, the BSE regulation, were provided to and discussed with you.

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Failure to correct these violations may result in FDA taking regulatory action without further notice including, but not limited to, seizure and/or injunction.

It is necessary for you to take action on this matter now. Please notify this office in writing within fifteen (15) working days from the date you received this letter. Your response should specifically identify the actions you are taking to correct the violations and provide specific timeframes for achieving compliance. Also, as part of your written response, you should provide information regarding the current feeding practices followed at your facility and information pertaining to the planned marketing of your animals. Your reply should be sent to Edwin Ramos, Compliance Officer, at the above stated address. If you have any questions concerning the stated matters, you may contact Mr. Ramos at 214-253-5218.

Sincerely,

Michael A. Chappe

Dallas District Director

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